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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,740	12/05/2001	Alexander MacGregor	23936-176	2553
20985	7590	09/22/2004	EXAMINER	
FISH & RICHARDSON, PC 12390 EL CAMINO REAL SAN DIEGO, CA 92130-2081			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1615	
DATE MAILED: 09/22/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/006,740

Applicant(s)

MACGREGOR, ALEXANDER

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-12,14-32,34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10-12,14-32,34 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some.* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of change in power of attorney, change of address, amendment and remarks filed 06/23/04. Claims 1, 3-8, 10-12, 14-32, 34 and 35 are pending.

Claim Rejections - 35 USC § 112

1. The rejection of claims 12, 17, 20, 24, 29 and 30 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the amendment. Applicant's analysis regarding the amended claims is persuasive.

Claim Rejections - 35 USC § 102

2. The rejection of claims 1, 3, 5 and 24 under 35 U.S.C. 102(b) as being anticipated by Fritsch et al. (US 5,213,794) is withdrawn because amended claim 1 recites ratio limitation, with respect to the hydrodynamic fluid imbibing polymer and hydrostatic pressure modulating agent, that is not disclosed by Fritsch and the rejection with respect to claim 33 is moot because of the cancellation of claim 33. Applicant's analysis as it relates to the amended claims is thus persuasive.

3. The rejection of claims 1, 3, 5, 7, 8, 11, 12, 14, 15, 18, 20, 21, 24-29, 31 and 32 under 35 U.S.C. 102(b) as being anticipated by Rork et al. (US 5,582,838) is withdrawn because amended claim 1 recites ratio limitation, with respect to the hydrodynamic fluid imbibing polymer and hydrostatic pressure modulating agent, that is not disclosed by Rork and the rejection with respect to claim 33 is moot because of the cancellation of claim 33. Applicant's analysis as it relates to the amended claims is thus persuasive.

Claim Rejections - 35 USC § 103

4. The rejection of claims 4, 6, 10, 16 and 19 under 35 U.S.C. 103(a) as being unpatentable over Rork et al. (US 5,582,838) is not maintained because Rork does not disclose the ratio limitation, with respect to the hydrodynamic fluid imbibing polymer and hydrostatic pressure modulating agent, as recited in the amended claim 1. Applicant's remarks with respect to the amended claims are persuasive.

The amendment to claim 1 where ratio limitation, with respect to the hydrodynamic fluid imbibing polymer and hydrostatic pressure modulating agent is recited, removes Fritsch and Rork as prior art over the amended claims. However, the new limitation gives rise to new matter rejection below.

NEW MATTER

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The recitation "wherein the weight ratio of said one, or more than one hydrodynamic fluid-imbibing polymer to said one, or more than one hydrostatic pressure modulating agent is from about 35:1 to about 170:1" introduces new matter into the claims.

6. Claims 1, 3-8, 10-12, 14-32, 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

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matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification supports a ratio of from about 99:1 to about 50:50 for the genus and support for the species for a ratio of from about 35:1 to about 170:1 does not provide support for the genus. The examples cited by the applicant cover one hydrodynamic fluid-imbibing polymer, CARBOPOL, and one hydrostatic pressure modulating agent, crospovidone and these single polymers do not support the concept of the genus as the genus relates to hydrodynamic fluid imbibing polymer and hydrostatic pressure modulating agent. The drug species in the examples do not provide support for the concept of genus with respect to agent of interest.

Suggestion:

A correction to “at least one” is respectfully requested as it regards “one, or more than one” as now recited in the amended claims versus “at least one” disclosed in the specification, at for example on page 5, lines 10 and 11.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Blessing Fubara
Patent Examiner
Tech. Center 1600



THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600